

***FACT SHEET FOR PATIENTS: UNDERSTANDING CDC HUMAN INFLUENZA VIRUS REAL-TIME RT-PCR DETECTION AND CHARACTERIZATION PANEL FOR RESPIRATORY SPECIMENS (NPS, NS, TS, NPS/TS, NA<sup>1</sup>) AND VIRAL CULTURE TEST RESULTS***

May 2, 2009

A public health emergency has been declared by the Secretary of Health and Human Services because of the 2009 outbreak caused by a novel H1N1 flu virus. "Novel" means that this virus was newly found. This virus is also referred to as swine influenza (H1N1) virus. This Fact Sheet will refer to the virus as novel H1N1 flu virus. The Food and Drug Administration (FDA) has authorized the emergency use of Centers for Disease Control (CDC) Human Influenza Virus Real-time RT-PCR Detection and Characterization Panel for Respiratory Specimens (NPS, NS, TS, NPS/TS, NA) and Viral Culture [rRT-PCR Flu Panel (NPS, NS, TS, NPS/TS, NA)] as a first tier test for the qualitative detection of influenza virus type A or B and subtype determination of seasonal human influenza A virus (seasonal A/H1 or A/H3) for individuals suspected of having a 2009 novel H1N1 influenza virus infection. This authorization will terminate on April 26, 2010, when the emergency has ceased to exist, or when the authorization has been revoked, whichever is earlier. The information in this Fact Sheet is the minimum necessary to inform you of any significant known and potential risks and benefits of the emergency use of the rRT-PCR Flu Panel (NPS, NS, TS, NPS/TS, NA).

**Why was my sample tested using the rRT-PCR Flu Panel (NPS, NS, TS, NPS/TS, NA)?**

There are no FDA cleared or approved tests that can be used as an initial test that uses the type of samples that your doctor may have collected from you. This test is a "first tier test" because it is the first test used with your sample. If this test is positive for influenza A but negative for seasonal A/H1 or H3, then your sample will be further tested for novel H1N1 flu virus. Your sample was tested using the rRT-PCR Flu Panel (NPS, NS, TS, NPS/TS, NA) because you may have been infected with novel H1N1 flu virus. This test could be a first step to help determine whether you are infected with novel H1N1 flu virus, so that public health officials can quickly identify a case and limit its spread. The results of this test, along with other information, may also help your doctor take better care of you.

**What is novel H1N1 flu?**

Novel H1N1 flu is a respiratory disease caused by type A influenza virus. Human cases of novel H1N1 flu virus infection have been identified in the United States and internationally. CDC has determined that this virus is contagious and is spreading from human to human. Like seasonal flu, novel H1N1 flu in humans can vary in severity from mild to severe.

**What is the rRT-PCR Flu Panel (NPS, NS, TS, NPS/TS, NA)?**

The rRT-PCR Flu Panel (NPS, NS, TS, NPS/TS, NA) is believed to perform as well as the test to detect seasonal influenza A/H1 or A/H3. The FDA has not cleared or approved this test. The FDA has cleared a similar test that is for use only with nasal swab or nasopharyngeal swabs. Because of limited availability of the cleared test, the FDA has authorized the emergency use of the rRT-PCR Flu Panel (NPS, NS, TS, NPS/TS, NA).

**What are the known risks and benefits of the rRT-PCR Flu Panel (NPS, NS, TS, NPS/TS, NA)?**

The results of this test from respiratory specimens (NPS, NS, TS, NPS/TS, NA) or viral culture, along with other information, can help your doctor take better care of you. Knowing your test results may help you to prevent the spread of the virus to your family or others. There may be no other benefits to you from this test.

**If the test is positive for seasonal flu, does that mean that I do not have novel H1N1 flu?**

If the test is positive for seasonal flu, you have been infected with common seasonal flu virus and it is likely that you do not have novel H1N1 flu. There is a small chance that this test can give a result that is wrong but should not affect your care. No changes in your medical care should be solely based on a negative result.

**If this test is positive, does that mean that I have novel H1N1 flu?**

If this test shows that you are infected with Influenza A but not the common seasonal flu virus, your specimen will be tested with the second test to determine whether you may be infected with novel H1N1 flu. Although there is a very small chance that this test can give a result that is wrong, it is not likely.

**If this test is negative, does that mean that I do not have novel H1N1 flu?**

If this test is negative, you may be sick with something that is not either seasonal flu or novel H1N1 flu. There is a small chance that this can give a result that is wrong (false negative). A false negative result should not affect your care. No changes in your medical care should be solely based on a negative result.

\*Any significant new findings observed during the course of the emergency use of CDC Human Influenza Virus Real-time RT-PCR Detection and Characterization Panel for Respiratory Specimens (NPS, NS, TS, NPS/TS, NA) and Viral Culture will be made available at <http://www.cdc.gov/h1n1flu/>.

<sup>1</sup> Nasopharyngeal swabs, nasal swabs, throat swabs, dual nasopharyngeal swabs/throat swabs, nasal aspirates.